Seascape®-BWMS Testing

Quality Assurance Project Plan of Sample Analysis

The First Institute of Oceanography, State Oceanic Administration

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Quality Assurance Project Plan of Sample testing of Seascape[®] -BWMS in the process of testing

Policy statement

The First Institute of Oceanography, State Oceanic Administration implements effective quality management according to quality policy and quality objective of "scientism, strict management, brand product, responsible service", which adopts ISO9001: 2000 quality control system.

Project content and quality requirements of sample testing in the process of testing of marine ballast water purification treatment (including land-based testing and shipboard testing) provided by Nantong Elite Marine ballast water management system Corp. is referred according to regulation D-2 of the "International Convention for the Control and Management of Ships' Ballast Water and Sediments" referred by "Guidelines for Approval of Ballast Water Management Systems (G8)". Quality Assurance Project Plan is written through earnest careful planning, enough scientific resources, which is required to ensure qualified personnel and effective instrument equipment, standard and regulation, enhance process control, implement strict internal quality examination and scrutiny, accept all proprietors' supervision and inspection consciously, ensure quality of results adequately.

Yuefen Yin from Marine Ecology Research Center is appointed as leader of quality assurance group, and implements quality management independently to ensure project quality compliance with the contract requirements according to GB/T19001-2000 standard quality system.

The First Institute of Oceanography, State Oceanic Administration

Superintendent: Deyi Ma

February 2012

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1. Introduction

1.1 Summary

The First Institute of Oceanography (FIO), State Oceanic Administration (SOA) is a public welfare party comprehensive marine research institution. "scientism, strict management, brand product, responsible service" is quality policy of scientific research and service activity. In recent five years, it is one of top hundred institutions. For many years, institution mainly engaged in various research, including following subjects: 1. Marine science basic research and applied basic research: researching natural environment factor distribution and change rule of China's offshore, adjacent sea areas and the polar ocean, marine resource distribution and formation mechanism; predicting marine disaster; studying Marine ecological environment change rule and control technology. 2. Service field: feasibility study of national defense and coastal nuclear power project, engineering investigation of ocean oil and gas exploration, feasibility study of harbor engineering environment, engineering investigation of gulf natural environment and coastal, ocean engineering environment parameters numerical simulation and statistical analysis, environmental impact assessment and environmental protection. Institution is obtained great scientific research and accomplishes sample tests of ballast treatment from many enterprises, which provides solid foundation to complete this project.

The First Institute of Oceanography has established and implemented sustainable improved performance quality management system considered all stakeholder needs, builds a systemic and visualized quality management and quality assurance system. Institute adjusted all kinds of laboratory organization and established a perfect investigation, analysis, testing quality system according to the metrological law of the People's Republic of China and the ISO/IEC guideline 25 "General standards of calibration and qualification of laboratory" in 1993. Institute passed assessment of the national quality technology supervision bureau, obtained national measurement authentication certificate, and had qualification to provide "CMA" logo and legal fair and accurate testing data for public in 1994. In 1995, Institute established and implemented a perfect quality management system gradually according to ISO 9000 international standard; completed three layers of quality system document. Due to the effective operation of the quality management system for many years, Institute ensures quality of science and technology achievements and products, and maintains good reputation. In order to adapt to the fierce market competition increasingly, "Beijing nine thousand standard quality system authentication center" called impartiality and authority is invited to review quality management system according to international practice, and Institute passed and completed the registration first time.

At the same time, institute gained and registered UKAS certificate from England royal authentication center and domestic certification. In 2001, institute turned quality management system certificate to 2000 versions, and finished registration certificate ISO9001:2000 edition.

Professor Ruixiang Li from the First Institute of Oceanography, SOA is responsible for this project. Main members own senior professional title and professional certificate, and pass training and strict examination. Based on the investigation and research technical requirements, working standards are all effective version of the international standard, national standards and trade standards. ISO 9001:2000 international standard and requirements of the First Institute of Oceanography of State Oceanic Administration are executed strictly in this project in order to control quality and processing, including different segments from technical scheme design to project implementation and so on. Institute implement and review in accordance with "contract", "embodiment", "quality assurance project plan". At the same time, quality audit and whole process of quality supervision and inspection are completed by quality management department of institute directly and independently, which guarantee the investigation data and report quality to meet the requirements of the contract or higher adequately.

1.1.1 The First Institute of Oceanography, SOA is a Public welfare party comprehensive marine research institution, which is a legal entity

- 1) Institutions organization code (certificate NO.42740670-4)
 - —— Issued by the national quality technology supervision bureau
- 2) Institutions legal person certificate (certificate NO.:11000000512)
 - —— Issued by national business unit registration administration

1.1.2 The First Institute of Oceanography, SOA own international and national class certificates

- 1) The People's Republic of China measurement authentication certificate (certificate NO...2013001317F)
 - —— Issued by national quality technology supervision bureau
- 2) The ISO9001:2000 quality system authentication certificate (registration NO.: 04005 Q12071ROM)
 - —— Beijing nine thousand standard quality system authentication center
- 3) Class B: environmental impact assessment certificate (NO. GHPZ2412)
 - —— Issued by National Environmental Protection Agency
- 4) Class A: Feasibility qualification certificate of sea area (certificate No.: 01003)
 - —— Issued by The state oceanic administration

1.1.3 Copies of qualification certificate related this project (Appendix)

1.2 Ranges

The quality assurance project plan is used to carry out quality assurance and quality control of this project including water quality, microbial, marine biological, and assure standards and regulations of major analysis, testing personnel quality and instrument equipment.

1.3 Responsibility

Undertaker of this project must make effective quality assurance project plan, and required principal (owner) to audit confirmation.

Undertaker of this project must establish special quality assurance groups consist of groupers with quality qualification and experience, is responsible for effective implementation of the quality assurance project plan, obligations and legal responsibility.

Scientific research, testing and technical personnel of this project are not only familiarity with observation of sampling, analysis, testing, material calculation and analysis, plotting maps, writing report and so on, but also have the height of responsibility and safety, quality consciousness, and is responsible for the quality.

2. Quality Assurance Project Plan

2.1 Summary

Institute control project quality according to requirements of ISO9001 standard and HYS quality system, adopt right method through effective implementation of necessary organization structure, process, procedure and the synthesis of resources, i.e. system method of process methods and management, put "process chain", "process network" and "process model" or system informed by interrelated process as a system of management control to ensure the purpose of quality and meet the contract.

2.2 Procedures and Conditions

Quality assurance work of this project is based on quality management system established by the First Institute of Oceanography, State Oceanic Administration (Q/CS quality management system documents 2008-01-15).

2.2.1 Measures for Quality Assurance

- **2.2.1.1** Quality assurance measures for field sampling
- All the samples are collected in the field.
- Sample water is divided to bottles designated for testing project. Bottles need be soaked with diluent hydrochloric acid and washed cleanly with pure water in advance to prevent contamination, and then rinsed with sea water twice before collecting in the field. The sample bottles of POC (include DOC) should be used glass bottles and analyzers should wear clean gloves during sampling. Bottles of microbial sample need be treated by high pressure sterilization in advance; More than 50 μm

organizations are filtered with nylon net of 50 μ m mesh(in the diagonal dimension) to concentrate, and then transited into a new plastic bottle with label. Between 10 μ m and 50 μ m organizations are filtered with nylon net of 10 μ m mesh (in the diagonal dimension) to concentrate, and then transited into a new plastic bottle with label.

- Method of detecting vivo-zooplankton is neutral red dye way.
- It is difficult to determine whether death according to cell for organizations no capacity to move (such as diatoms, etc.), some methods can be matched to determine vivo-organizations, including FDA-PI dye. If possible, photosynthetic efficiency (F_v/F_m) , chlorophyll is measured, as well MPN cultivation.

2.2.1.2 Quality assurance measures of sample transportation and storage

Measures of preventing pollution are adopted for sample filtering and repacking operation. The samples for water quality are not analyzed in the field except temperature and salinity. Water samples of TSS, POC and DOC(no in shipboard testing) are pre-treated (filtered) in the field laboratory. Every sample above fiber membrane is put in sealed plastic bag with label and put into freezer on the board to freeze. All samples of TSS, POC and DOC are taken from freezer on the field lab and shifted to an ice box added dry ice (or ice bags) and transported to laboratory in Qingdao when the testing finish.

Plankton samples for ballasting stage is fixed with fixed agent and sealed into a box to transit to laboratory under the ambient temperature. While Plankton samples for discharging are not added any fixed agent and stored into freezer of 4~% or an incubator in which are added ice bags.

The transportation of samples should be transported to by special person.

2.2.1.3 Quality assurance measures of laboratory measurement and data analysis

- 1) Various analysis and data are based on requirements of "Specifications for Oceanographic Survey, part 5: marine chemical survey and part 6: marine biological survey" (GB/T-12763.4-2007, GB/T12763.6-2007, National standard of China), "Specifications for Oceanographic Monitoring" (GB17378. 2007, National standard of China) and ISO 7899-2-2000 "Water quality Detection and enumeration of intestinal enterococci", as well ISO 9308-1-2000" Water quality Detection and enumeration of *Escherichia coli* and coliform bacteria".
- 2) Calculation of various sample analysis data is based on effective calculation method. The calculation results must be pass examination and verification.

2.2.1.4 Quality control of sample collection and analysis

- 1) All the professional operation observes relevant regulations or standard. All professional testing data take effect after professional expert's audit.
 - 2) Control of sample analysis
 - All instruments used to analysis will meet the project requirement.

- Sample need inspect before test, requirement: internal and external mark of sample must correspond with sampling records in the field, and complete.
- Instrument equipment of analysis and testing must be normal after finishing sample analysis.
- It is timely to analyze the reason, and make a reasonable analytical and conclusion when testing results appear unusual, if necessary, re-examine.

2.2.2 Equipment Configuration and Control

Equipment of this project must comply with the state's relevant guidelines and regulations of accuracy before use. The working procedures of equipment must be drafted, and observed strictly to ensure security of equipment and personnel, accuracy of records, information and data.

Methods and instruments of this project shall meet the following conditions

- A. All the methods adopted in this project are subject to rules and regulations or scientific method accepted.
- B. All kinds of instruments and equipment of this project passed inspection and verification of the quantitative, and comply with the relevant state provisions and requirements of guide.
- C. Sensitivity of instrument is ensured to meet the requirements of the HAD0103 documents.

2.3 Examination of Management Department

The project process is tracked and reviewed by science and technology development office of the First Institute of Oceanography, State Oceanic Administration and department of quality management according to regulations of ISO9001:2000 quality management system

2.3.1 Examination of Instrument and Equipment

Audit and registration system of instrument equipment is implemented in the process of implementation strictly by department of Science and technology development to ensure norm of application equipment and meet technical requirement in the effective period.

2.3.2 Audit of "Implementation Plan" and "Quality Assurance Project Plan"

Experts of Science and technology development management office audit implementation scheme to achieve requirements of implementation plan and quality assurance project plan, including whether to meet requirements of application methods and instrumentation in contract, whether to conform to the standard, whether advanced.

2.3.3 Audit of Project Members

Implement the project leader responsibility system, members have qualification, carry on job training, clear post responsibility; the special quality assurance team is

equipped, members are independent outside of the project, which ensure implementation of "contract" "implementation plan" and "quality assurance project plan".

2.3.4 Audit of Project Analysis Result

Acceptance check system of second level check and first level review is implemented in this project, i.e. middle audit and final audit of assay determination, acceptance check of final results. Related experts organized by department of science and technology development review intermediate stage results and final results, which ensure that project data and report quality meet or exceed requirements of contract. Party A organization review project result.

2.4 Management of Quality Assurance Project Plan

The quality management department is responsible for management of quality assurance project plan. Leader of quality assurance team is responsible for management of daily quality assurance work. The quality assurance documents and records are handed to archives information center of institute to keep.

3. Organization

3.1 Responsibility, Competence and Structure

3.1.1 Structure Block Diagram of Project Organization

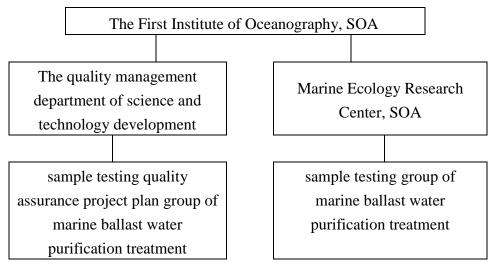


Fig. 3-1 Structure block diagram of project organization

3.1.2 Quality Responsibility

Chief scientist system is implemented for projects, and chief scientist (project leader) bears overall responsibility for the quality of projects, must guarantee that project result quality meet requirements of technical contract and the relevant laws and regulations.

Project participants undertake main responsible for specific work quality, and guarantee process in accordance with the technical standards and operational procedures.

Quality assurance leader undertake total responsible for quality control and quality superintendent of all the process.

Members of quality assurance team undertake main responsible for quality control and quality superintendent.

3.2 Researchers and Training

3.2.1 Quality Assurance Team

Leader:

Lang Li, vice- director, the quality management department of the First Institute of Oceanography, SOA

Vice-leader:

Heping Yin, department of science and technology development of the First Institute of Oceanography, SOA.

Member:

Ruixiang Li, professor, the key laboratories of marine ecological environmental science and engineering

Zheng Li, vice-director, the key laboratories of marine ecological environmental science and engineering

Yuefen Yin, associate researcher, the key laboratories of marine ecological environmental science and engineering

3.2.2 Member of Project

See appendix 1 for leader and members of project and qualification.

In addition, some post graduates and PhD students will also attended to this project work. Although all students have not certificate, but they must be participate the professional training and have ability and experience of marine monitoring.

Appendix 1: list of testing personnel qualifications

No.	Name	Title	Undertake content of project	Certificate	Certificate No.	Certifying authority	Date of issue
1	Ruixiang Li	prof.	marine organisms	Qualification certificate of marine test technical personnel	/	Department of Science and Technology,SOA	1994.10
2	Baodong Wang	prof.	feasibility qualification certificate of sea area	Qualification certificate of marine environment investigators	/	Department of Science and Technology,SOA	1994.10
3	Jinxing Zhang	prof.	responsible for microbes	Qualification certificate of marine environment investigators	/	Department of Science and Technology,SOA	1994.10
4	Yan Li	associate researcher	10 μm-50 μm plankton	Qualification certificate of marine environment investigators	B0034	Center of National Oceanic Standard	2006.06
5	Xia Sun	assistant researcher	Analysis of water quality	Qualification certificate of marine environment investigators	C0121	Center of National Oceanic Standard	2006.06
6	Ping Sun	assistant researcher	10 μm-50 μm phytoplankton	Qualification certificate of marine test technical personnel	68156	Center of National Oceanic Standard	2006.06
7	Lingyun Qu	prof.	microbes	Qualification certificate of marine environment investigators	B0231	Center of National Oceanic Standard	2006.06
8	Linping Xie	assistant researcher	Analysis of POC, DOC	Qualification certificate of marine environment investigators	11068	Center of National Oceanic Standard	2009.05
9	Ping Liu	assistant researcher	>50 µm plankton	Qualification certificate of marine environment investigators	11082	Center of National Oceanic Standard	2009.05
10	Hongjun Song	doctor	10 μm-50 μm phytoplankton	Qualification certificate of marine environment investigators	B0166	Center of National Oceanic Standard	2006.06
11	Bin Xia	senior engineer	Chlorophyll a	Qualification certificate of marine environment investigators	/	Department of Science and Technology,SOA	1994.10

4. Document Control

4.1 Summary

The standards and specifications, technical documents used in this project should be formal effective version, the copy should be confirmed by quality management department; the calculation software used in this project is mature and popular software package. All documents must be archived and unified management, including original material, important process data, "contract", "implement plan", "quality assurance project plan" etc.

4.2 Writing Audit and Approval of Documents

Detailed implementation plan is formulated and submitted to competent department according to "working outline" and "quality assurance project plan", and implemented after approval of leadership and owner.

Data processing and compiling report are implemented after passing check and accept qualification basis on technical standard quality and signature of principal. Project team should apply for final inspection to related business department organization after finishing analysis report. Marine environment test center of the First Institute of Oceanography, SOA provide test report after passing final examination and signature.

4.3 Storage of Document

A set of complete file will be archived in information center after audit and approval of documents.

5. Process of Monitoring and Control

In order to guarantee the quality of products that reaches the requirements, this control is an important means of control, and it is the product form and submit to the customer influence on the overall process directly.

5.1 Control of Process Monitoring

Technical disclosure to the testing personnel, clarify their respective duties and responsibilities.

After instrument and equipment enter the area, see if it comes to normal. Instrument should be checked again after installation in place, make correction/calibration and record.

Operating personnel should accord by the standards that meet the requirements and the scheduled operation which is effective standards version of the instructions.

Samples should be put with the request and the logo.

After the completion of the observation, it should check the equipment whether in good condition.

5.2 Control of Publishing Process

Results should achieve the language refining, accuracy of language expressions, Text and the maps are clear and aesthetic, don't appear error page, Units with national standard, decorating is exquisite and practical, and disk backup with floppy.

6. Control of Check and Test

6.1 Outline of Check and Test

Control of the detection accuracy, ensure the implementation of the detection device or equipment up to the required capacity, and provide evidence for product meets the requirements.

6.2 The Control of Testing Equipment

- 6.2.1 All the instruments and equipment are verified by the national legal institutions; ensure to use it in the validity period. Before use self-test equipment, let professionals to compare measure and calibration.
- 6.2.2 All observation instruments are prepared to spare instruments, and provide the spare parts with wearing parts.
- 6.2.3 After the damage of the instrument was maintained, compare measure and calibration by professionals.

7. Control of Nonconformities

7.1 Summary

ISO9001:2000 standard and program files are implemented seriously,

Q/CS-B5.6-01-2008 "Monitoring and measuring control program",

Q/CS-B5.7-01-2008 "Monitoring and measuring data quality control program",

Q/CS-B5.5-01-2008 "Identification and traceability control program",

Q/CS-B5.7-02-2008 "Control of nonconformities",

Q/CS-B4.9-01-2008 "Corrective measures to control the process" and

Q/CS-B4.8-02-2008 "Preventive measures to control the process" and so on, Strict control, so prevention, reduce or avoid the unqualified, ensure the effectiveness of the implementation and efficiency of continuous improvement and sustainable improvements in quality.

7.2 Non-conformities Logo, Review and Processing

- **7.2.1** When find non-conformance, the parties may not conceal it, the parties should report to the charge on the spot immediately, Major non-conformity should report relevant leaders, report to party as necessary. Fill in non-conformity report truly.
- **7.2.2** Science and technology development and quality assurance group in relevant personnel in conjunction with the project team relevant personnel check the situation of the non-conformity, Analysis the causes of non-conformity.

- **7.2.3** From the above personnel assess the extent of the non-conformance and determine treatment measures, general non-conformity can receive concessions, major non-conformity shall be invalid, check again.
- **7.2.4** Make preventive and corrective measures, prevent non-conformance to happen again.

8. Corrective Measures

Analyze the causes of non-conformity, take necessary corrective measures, and prevent non-conformance and new non-conformance to happen again.

8.1 Corrective Measures

When nonconforming products appear, relevant personnel of the project should implement effective control of non-conformity and mark to products, prevent the nonconforming product is unexpected to use and delivery.

For instrument equipment failure or damage which is interrupted operations, we can use the same level or meet the requirements of the work project of the substitute instruments and equipment to re-investigation. When no alternative equipment, the damage equipment can re-use after repair and qualified.

In order to prevent the occurrence of non-conformity, proposed the following preventive measures.

- a) All operators must have certificates,
- b) Repair test instruments and equipment regularly,
- c) Quality assurance group should regularly check the implementation of carry out the situation of preventive measures.

9. Records

After this program working, all events must have quality assurance records, it contains analysis results records of testing, monitoring and implementation work. All quality assurance records must legible, complete, and the items or service corresponds.

- 1) Original records are recording of test results truly, do not allowed change optionally, no cut, do not permit other organizations to look up original records. Technical leader have right to check original records and give suggestions.
- 2) The form of original records are uniformed, do not use pencil to fill in it(Except the provisions), content should fill in completely, the signature must contains survey, the examination and calibration of personnel.
- 3) Approving authority must approve the survey and data of detection, any project can be detected repeat, the approving volume shall not be less than 5%.
- 4) Original records need to indeed change, two level should be written on delete data, the right data are filled in the above, Change rate shall be less than 3%.

- 5) Original records sent to file in willmigerl after give out the detection report, retention period shall not less than two years.
- 6) Strictly implement GB/T-12763-2008 standard and the "Marine monitoring standards" regulation, so that confirm the detection data of significant digits,

10. Monitoring

It must take measures to verify the implementation and its effectiveness of quality assurance program, Verify if it compliances with quality assurance program in all aspects and determines the effectiveness of the program.

10.1 Monitoring of internal Quality

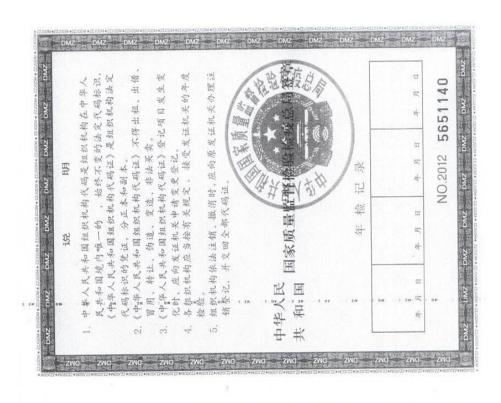
a) This project is equipped with complete quality assurance system, build quality assurance team, provided fulltime quality assurance personnel, the entire personnel and overall process implement the control of quality. They implement quality assurance monitoring in overall process independently, they are only responsible for quality, survey the quality of items achievement can guarantee sufficiently.

10.2 Monitoring of external Quality

- b) Accept the monitoring of supervisor entrusted by the owner, show quality records, the unqualified project was corrected timely.
 - c) Accept the monitoring of quality supervision unit to check and check out.

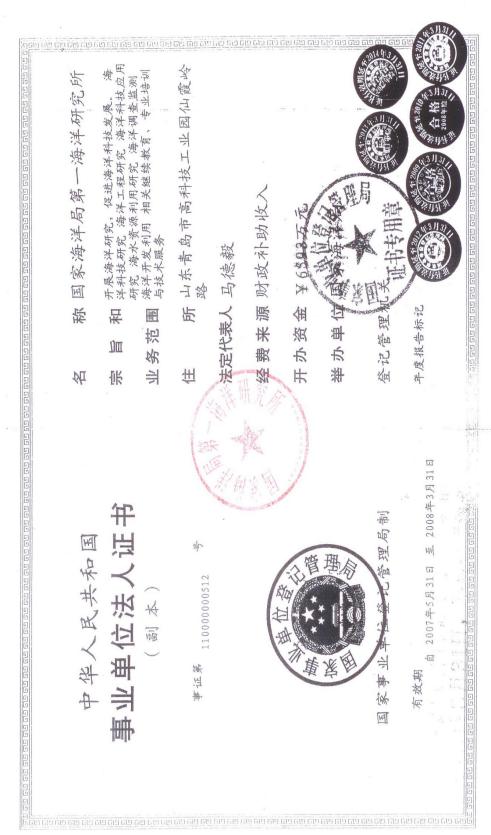
Appendix2:

1) Institutions organization code





2) Institutions legal person certificate



3) Measurement authentication certificate



资质认定

计量认证证书

证书编号: 2013001317F

名称: 国家海洋局第一海洋研究所海洋环境测试中心

地址: 山东省青岛市仙霞岭路 6号(266061)

经审查, 你机构已具备国家有关法律、行政法规 规定的基本条件和能力, 现予批准, 可以向社会出具 具有证明作用的数据和结果, 特发此证。

检测能力见证书附表。

(你机构对外出具检测报告的法律责任由国家海洋局第一海洋研究所承担。)

准许使用徽标





本证书由国家认证认可监督管理委员会制定,在中华人民共和国境内有效

4) ISO9001:2000 quality system authentication certificate





QUALITY MANAGEMENT SYSTEM **CERTIFICATE**

Certificate No.: 00111Q212188R0M/3700 We hereby certify that

THE FIRST INSTITUTE OF OCEANOGRAPHY, SOA, CHINA

No.6 Xianxialing Road, Hi-Tech Industrial Park, Qingdao City, Shandong Province, P.R. China

Quality Management System
has been awarded this certificate for compliance with the standard

ISO9001: 2008

GB/T 19001-2008
The Quality Management System Applies in the following area:

Marine Science Research

Valid from: Dec. 26, 2011 Valid until: Dec. 25, 2014 Certified since: Dec. 26, 2011









CHINA QUALITY CERTIFICATION CENTRE

5) Environmental impact assessment certificate



6) Feasibility qualification certificate of sea area

